This submission is in response to the Restriction Requirement dated July 16, 2002. Claims 1-26 are pending. Claim 9 has been amended to correct dependency from claim 9 to claim 8. No new matter has been added by this amendment. Therefore, entry of this amendment is respectfully requested.

The Examiner has required restriction to one of the following groups of claims under 35 U.S.C. §121:

- I. Claims 1-4, 9, 22 and 26, drawn to methods of treatment comprising administering a chemokine.
- II. Claims 5-8, and 23-25, drawn to compositions comprising a chemokine.
  - III. Claims 14-17, drawn to antibodies.
- IV. Claims 10-13 and 18-21, drawn to methods for treatment comprising administering an antibody.

In order to be fully responsive to the restriction requirement, Applicants hereby elect to prosecute claims 1-4, 9, 22 and 26, corresponding to Group I, without traverse.

#### **CONCLUSION**

Applicants respectfully request entry of the foregoing amendment and remarks into the file history of this application. In view of the above remarks, an early action on the merits is courteously solicited.

Respectfully submitted,

Paul F. Fehlner, Ph.D.

Reg. No. 35,135

Attorney for Applicants

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lawrence PAPSIDERO; Lyn DYSTER;

Jana FRUSTACI

Serial No.:

09/834,794

Art Unit:

1642

Confirmation No.: 1046

Filed: April 13, 2001

Examiner:

HOLLERAN, Anne

HUMAN CHEMOKINE AND ITS USE FOR DETECTION AND TREATMENT OF

**BREAST DISEASE** 

### **MARK-UP AMENDMENT**

Hon. Commissioner of Patents and Trademarks Washington, DC 20231

November 18, 2002

Sir:

IN THE CLAIMS

A method for treating breast disease in a patient in need 9. (Amended) thereof, which method comprises administering the dosage unit form according to claim [9] 8.



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**BREAST DISEASE** 

## **COURTESY COPY OF PENDING CLAIMS** (NON-ELECTED CLAIMS ARE ITALICIZED)

Hon. Commissioner of Patents and Trademarks Washington, DC 20231

November 18, 2002

Sir:

1. A method for treating breast disease in a patient in need thereof, which method comprises administering to the patient an effective amount of a chemokine, which chemokine has about 105 to about 127 amino acids, has a deduced

molecular weight of from about 12 to about 14 kD, has a deduced isoionic point of from about pH 10.1 to about pH 10.7, and comprises at least one amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5; wherein the breast disease is selected from the group consisting of

2. The method according to claim 1, wherein the chemokine has an amino acid sequence comprising each of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5.

benign cystitis, benign hyperplasia, cancer and malignancies.

- 3. The method according to claim 2, wherein the chemokine has an amino acid sequence as depicted in SEQ ID NO:1.
- 4. The method according to claim 1, wherein the peptide is administered orally, parenterally, subcutaneously, intravenously, intramuscularly, intraperitoneally, intraocularly, intraarterially, by intranasal instillation, by intracavitary instillation, by intravesical instillation, or by application to mucous membranes.
- 5. A composition comprising a chemokine, wherein the chemokine has about 105 to about 127 amino acids, has a deduced molecular weight of from about 12 to about 14 kD, has a deduced isoionic point of from about pH 10.1 to about pH

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- 10.7, and comprises at least one an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5, wherein the peptide is present in the composition in an amount effective to treat a breast disease.
- 6. The composition according to claim 5, further comprising at least one component selected from the group consisting of carriers, excipients, diluents, binders, disintegrating agents, lubricants, adjuvants, surfactants, propellants, and stabilizers.
- 7. A dosage unit form comprising the composition according to claim 6.
- 8. The dosage unit form according to claim 7, selected from the group consisting of tablets, capsules, powders, solutions, suspensions, aerosols, and emulsions.
- 9. A method for treating breast disease in a patient in need thereof, which method comprises administering the dosage unit form according to claim 8.
- 10. A method for treating breast disease in a patient in need thereof, which method comprises administering to the patient an effective amount of an antibody

or a binding portion thereof which recognizes a chemokine, wherein the chemokine has about 105 to about 127 amino acids, has a deduced molecular weight of from about 12 to about 14 kD, has a deduced isoionic point of from about pH 10.1 to about pH 10.7, and comprises at least one an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5; wherein the breast disease is selected from the group consisting of inflammation, infection, and

- 11. The method according to claim 10, wherein the chemokine has an amino acid sequence comprising each of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5.
- 12. The method according to claim 11, wherein the chemokine has an amino acid sequence as depicted in SEQ ID NO:1.
- 13. The method according to claim 10, wherein the antibody or binding portion thereof is administered orally, parenterally, subcutaneously, intravenously, intramuscularly, intraperitoneally, intraocularly, intraarterially, by intranasal instillation, by intracavitary instillation, by intravesical instillation, or by application to mucous membranes.

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mastitis.

- 14. A composition comprising an antibody or a binding portion thereof which recognizes a chemokine, wherein the chemokine has about 105 to about 127 amino acids, has a deduced molecular weight of from about 12 to about 14 kD, has a deduced isoionic point of from about pH 10.1 to about pH 10.7, and comprises at least one an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5, wherein the antibody or binding portion thereof is present in the composition in an amount effective to treat a breast disease.
- .15. The composition according to claim 14, further comprising at least one component selected from the group consisting of biological agents, carriers, excipients, diluents, binders, disintegrating agents, lubricants, adjuvants, surfactants, propellants, and stabilizers.
- 16. A dosage unit form comprising the composition according to claim 14.
- 17. The dosage unit form according to claim 16, selected from the group consisting of tablets, capsules, powders, solutions, suspensions, aerosols, and emulsions.

- 18. A method for treating breast disease in a patient in need thereof, which method comprises administering the dosage unit form according to claim 17.
- 19. The method according to claim 11, wherein the antibody is conjugated to a cytotoxic drug.
- 20. The method according to claim 19, wherein the cytotoxic drug is selected from the group consisting of a therapeutic drug; a radioactive compound; a molecule of plant, fungal, or bacterial origin; a biological protein; and mixtures thereof.
- 21. The method according to claim 12, wherein the method is used in conjunction with surgery, radiation, crysosurgery, thermotherapy, hormone treatment, chemotherapy, and vaccines.
- 22. A method for vaccinating against a breast disease in a patient in need thereof, which method comprises administering to the patient an effective amount of an antigenic portion of a chemokine with an effective amount of an adjuvant, wherein the chemokine has about 105 to about 127 amino acids, has a deduced molecular weight of from about 12 to about 14 kD, has a deduced isoionic point of from about pH 10.1 to about pH 10.7, and comprises at least one amino acid

sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5; wherein the breast disease is selected from the group consisting of inflammation, infection, and mastitis.

- 23. A composition comprising (i) an antigenic portion of a chemokine, wherein the chemokine has about 105 to about 127 amino acids, has a deduced molecular weight of from about 12 to about 14 kD, has a deduced isoionic point of from about pH 10.1 to about pH 10.7, and comprises at least one an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5, wherein the antigenic portion of a chemokine is present in the composition in an amount effective to vaccinate against a breast disease; and (ii) an adjuvant.
- 24. A dosage unit form comprising the composition according to claim 23.
- 25. The dosage unit form according to claim 24, selected from the group consisting of tablets, capsules, powders, solutions, suspensions, aerosols, and emulsions.
- 26. A method for vaccinating against a breast disease in a patient in need thereof, which method comprises administering the dosage unit form according to

claim 25.